

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Jon Ocel et al.

Examiner: Peter J. Vrettakos

Serial No.: 10/056,807

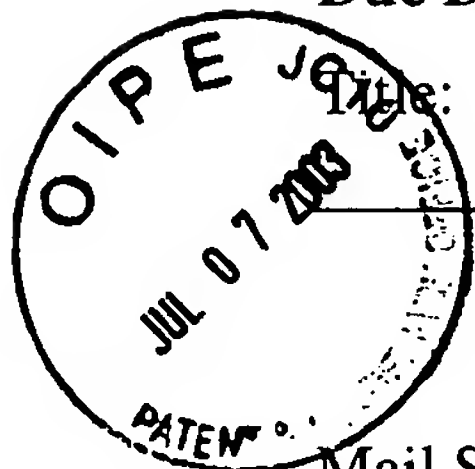
Group Art Unit: 3739

Filed: January 25, 2002

Docket No.: M190.134.101

Due Date: July 23, 2003

Title: FLUID-ASSISTED ELECTROSURGICAL INSTRUMENT WITH
SHAPEABLE ELECTRODE



RESPONSE

Mail Stop Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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JUL 15 2003

TECHNOLOGY CENTER R3700

Dear Sir:

This is responsive to the non-final Office Action mailed April 23, 2003. In that Office Action, the Examiner rejected claims 1-43 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 12 was also rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Further, the Examiner rejected claims 1-4, 7-11, 13-18, 24-31, and 33-43 under 35 U.S.C. § 102(b) as being anticipated by Hovda et al., U.S. Patent No. 6,053,172 ("Hovda"). Claims 1-11, 13-16, and 24-32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hovda in view of Panescu et al., U.S. Patent No. 5,688,267 ("Panescu"). Claim 19 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Hovda in view of Moaddeb et al., U.S. Patent No. 6,405,078 ("Moaddeb"). It is believed that all claims are in a condition for allowance for the reasons stated below.

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35 U.S.C. § 112, First Paragraph Rejections

Claims 1-43 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the Specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. In particular, the Examiner rejected the Specification as neglecting to adequately disclose the characteristics and materials that constitute the shaft, which permit it to independently maintain shape. The Applicants respectfully request the Examiner's rejection of claims 1-43 be withdrawn for the reasons below.

In one preferred embodiment of the Specification, the shaft 22 includes an elongated electrode body 60 and an electrical insulator covering 62 as shown in FIGS. 1 and 3. (Page 12, lines 20 to 23). In that embodiment, the electrode body 60 is formed of a material, such as stainless steel or nitinol, which is malleable. (Page 13, lines 1 to 21). The term "malleable," as used in the Specification, necessarily means malleable enough to be formed by a surgeon prior to ablation, yet able to resist deformation from forces associated with the ablation process. (See page 12, lines 11 to 19). Stainless steel has the requisite malleability to permit the shaft to independently maintain its shape and is readily identifiable to one of ordinary skill in the art. Nitinol is known to one of ordinary skill in the art as a "shape memory" metal able to transition between bent states, yet able to resist relatively low-force deformation. As such, disclosure of nitinol as a material forming a predominate portion of the shaft also enables a shaft that is transitionable to a bent state and capable of independently maintaining distinct shapes. Finally, in such an embodiment the insulator covering 62 is described as being made of a flexible material that does not impede shaping and re-shaping of the electrode body 60. (Page 13, lines 18 to 21). Therefore, the Specification discloses preferred embodiments, including materials with the requisite characteristics, which enable the shaft to independently maintain shape. For at least these reasons, the Examiner's rejection of 1-43 is respectfully traversed as the description is sufficient to enable any person skilled in the art to make and use the malleable shaft.

Claim 12 was rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the Specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. The Examiner cited the following language of claim 12 as lacking clarity: "The rigid coupling...the tip is readily manipulated in a

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sliding fashion via movement of the handle....” In particular, the Examiner rejected the specification as failing to enable, absent further clarification. It is respectfully submitted that the Examiner withdraw rejection of claim 12 under 35 U.S.C. 112, first paragraph, for at least the reasons stated below.

In one embodiment defined in the Specification, the shaft 22 is rigidly affixed to the handle 20 and the tip 44 is rigidly affixed to the shaft. (Page 14, lines 25 to 26; and page 19 lines 1 to 6). In such an embodiment, moving the handle inherently moves the tip because of the rigid connections between the handle, shaft, and tip. As such, movement of the handle may be performed in such a manner as to slide or drag the tip across tissue. (Page 19, lines 4-6). Methods of rigid connection between such components are well known in the art and include at least: welding, laser welding, spin welding, crimping, gluing, soldering and press fitting. (Page 14, lines 21-23). Therefore, the Specification describes an embodiment wherein the tip is readily manipulated in a sliding fashion via movement of the handle so as to enable one of ordinary skill in the art to make and/or use the invention. As such, the Examiner’s rejection of claim 12 under 35 U.S.C. § 112, first paragraph is respectfully traversed. Claim 12 is both supplied with sufficient clarity and enabled by the Specification so as to meet the requirements of 35 U.S.C. § 112, first paragraph.

35 U.S.C. §§ 102(b) and 103(a) Rejections

Claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by Hovda and under 35 U.S.C. § 103(a) as being unpatentable over Hovda in view of Panescu. Claim 1 relates to an electrosurgical instrument including an elongated shaft adapted to be transitionable from a straight state to a first bent state and able to independently maintain distinct shapes in the straight state and the first bent state. For the reasons below, Hovda does not expressly or inherently teach or suggest such limitations.

Hovda only teaches or suggests (1) a flexible shaft or (2) a rigid shaft. Hovda states that a shaft suitably designed to access the larynx will be flexible or have a distal bend. (Column 11, lines 30-34). Hovda then states in that in this regard the shaft may be a rigid shaft with a specific bend, a rigid shaft with a flexible distal end, or a shaft that is part of a catheter. (Column 11,

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lines 32-35). In contrast to a rigid shaft with a specific bend, a flexible distal end and a flexible catheter may teach a flexible shaft or a transitionable shaft, but not a transitionable shaft that independently maintains distinct shapes as required by claim 1.

Further, Hovda only discloses using flexibility (1) to allow actuation; (2) presumably to “snake” the electrodes in a manner similar to that of a catheter; or (3) in combination with a rigid member for support. Such flexible shafts are referred to as completely flexible or flexible and supported by an external means. (Column 11, lines 5-10). Such support is accomplished by combining a flexible shaft with “mechanisms” for manipulating the distal end or “a generally rigid external tube for mechanical support.” (Column 11, lines 7 to 9). These “mechanisms” include pull wires, shape memory actuators, and other known mechanisms for effecting selective deflection. (Column 11, lines 8-11; column 17, lines 53-59). Absent a mechanism maintaining deflection, the distal end merely flexibly deflects upon application of any force. Hovda teaches that these mechanisms would be used to maintain bent states in the flexible shaft. Obviously, a shape memory actuator would not only induce deflection, but also maintain such deflection in the flexible shaft. However, utilization of such mechanisms in addition to the shaft structure fails to meet the limitations of claim 1, which requires a shaft adapted to be both transitionable from a straight state to a first bent state and able to independently maintain distinct shapes in the straight state and the first bent state. In fact, teaching the use of additional external members or mechanisms teaches away from maintaining such bends independently.

Panescu similarly teaches away from claim 1 by teaching shaft flexibility only in association with steerable catheter embodiments that do not disclose or suggest a shaft able to independently maintain distinct shapes. (See column 4, line 63 – column 5, line 18). As a result, Panescu fails to teach or suggest a shaft adapted to be transitionable from a straight state to a first bent state, the shaft independently maintaining distinct shapes in the straight state and the first bent state.

The Hovda disclosure, taken as a whole, does not anticipate a transitionable shaft that independently maintains its shape following transition to a bent state; in fact, Hovda teaches away from such a limitation. Neither does the Panescu reference teach or suggest a limitation. For at

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least the above described reasons, the Examiner's rejections of claim 1 under 35 U.S.C. §§ 102(b) and 103(a) are traversed, and claim 1 is believed to be allowable.

Claims 2-11 and 13-18 were rejected under 35 U.S.C. §§ 102(b) and/or 103(a). Each of these claims depends from claim 1, which, as previously described, is not taught or otherwise suggested by the cited references. Therefore, the rejection of claims 2-11 and 13-18 is respectfully traversed, and claims 2-11 and 13-18 are believed to be allowable.

Claim 19 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Hovda in view of Moaddeb. Claim 19 depends from claim 1, which, as previously described, is not taught or otherwise suggested by Hovda. Similar to Panescu, Moaddeb teaches away from the limitations of claim 1 by teaching flexibility only in association with steerable catheter embodiments. (See FIGS. 1, 2, 3A, 3B, 5, and column 5, line 25 – column 6, line 44). Therefore, Moaddeb does not supply the requisite motivation for modifying Hovda to include a transitionable shaft, able to independently maintain shape. Therefore, rejection of claim 19 is respectfully traversed and claim 19 is believed to be allowable for the above stated reasons.

Claim 24 was rejected under 35 U.S.C. § 102(b) as being anticipated by Hovda and under 35 U.S.C. 103(a) as being unpatentable over Hovda in view of Panescu. Claim 24 relates to an electrosurgical system including an electrosurgical instrument including an elongated shaft adapted to be transitionable from, and independently maintain a shape in, a straight state and a first bent state. Such limitations are not taught or otherwise suggested by the cited references for reasons similar to those described with regard to claim 1. In particular, the cited references require external mechanisms or members to maintain a shape of a flexible shaft in a straight state and a first bent state, thus failing to do so independently as required by claim 24. Consequently, the Examiner's rejection of claim 24 is respectfully traversed, and claim 24 is believed to be allowable.

Claims 25-32 were rejected under 35 U.S.C. §§ 102(b) and/or 103(a) as being anticipated by Hovda and unpatentable over Hovda in view of Panescu. Each of claims 25-32 depends from claim 24, which, as previously described, is not taught or otherwise suggested by the cited references. Therefore, the rejection of claims 25-32 is respectfully traversed, and claims 25-32 are believed to be allowable.

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Claim 39 was rejected under 35 U.S.C. § 102(b) as being anticipated by Hovda. Claim 39 relates to a method of performing an electrosurgical procedure including providing an electrosurgical instrument including an elongated shaft that may be bent to a first bent state in which a portion of the shaft is deflected relative to the linear axis, wherein the shaft independently maintains a shape of the first bent state. Such limitations are neither taught nor suggested by the cited references for reasons similar to those described in regard to claim 1. In particular, the cited references require external mechanisms or members to maintain a shape of a flexible shaft in a straight state and a first bent state; thus failing to do so independently as required by claim 39. Consequently, the Examiner's rejection of claim 39 is respectfully traversed and claim 39 is believed to be allowable.

Claims 40-43 were rejected under 35 U.S.C. § 102(b) as being anticipated by Hovda. Each of claims 40-43 depends from claim 39, which, as previously described, is not taught or otherwise suggested by the cited references. Therefore, the rejection of claims 40-43 is respectfully traversed and they are believed to be allowable for the same reasons as claim 39.

CONCLUSION

In light of the above, Applicant believes independent claims 1, 24 and 39 and the claims depending therefrom (claims 2-23, 25-38, and 40-43) are in condition for allowance. Allowance of these claims and notice to that effect is respectfully requested.

No fees are required under 37 C.F.R. 1.116(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 500471.

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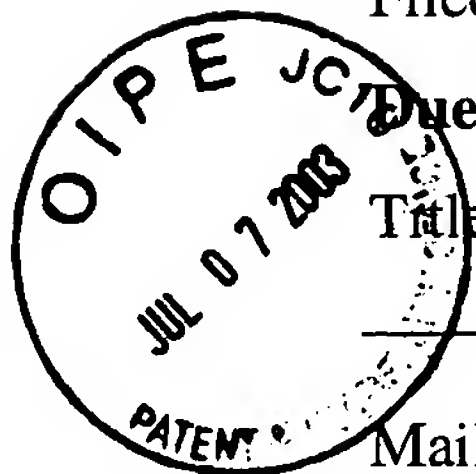
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Sir/Madam:

We are transmitting herewith the attached:

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- ☒ Transmittal Sheet containing Certificate of Mailing (1 pg.).
☒ Response (7pgs.);
☐ Other:
☒ Two (2) Return Postcards.

If an additional fee is required due to changes to the claims, the fee has been calculated as follows:

CLAIMS AS AMENDED						
	(1) Claims Remaining After Amendment		(2) Highest Number Previously Paid For	(3) Present Extra	Rate	Fee
TOTAL CLAIMS	43	-	43	0	x 18.00 =	\$0.00
INDEPENDENT CLAIMS	3	-	3	0	x 84.00 =	\$0.00
[] MULTIPLE DEPENDENT CLAIMS PRESENTED						\$0.00
TOTAL						\$0.00

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers, if appropriate. At any time during the pendency of this application, please charge any additional fees or credit overpayment to Deposit Account No. 500471.

Customer No. 025281

By:

Name: Timothy A. Czaja

Reg. No.: 39,649

CERTIFICATE UNDER 37 C.F.R. 1.8: The undersigned hereby certifies that this paper or papers, as described herein, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 30 day of July, 2003.

By:

Name: Timothy A. Czaja

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The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this response.

Respectfully submitted,

Jon Ocel et al.,

By their attorneys,

DICKE, BILLIG & CZAJA, PLLC

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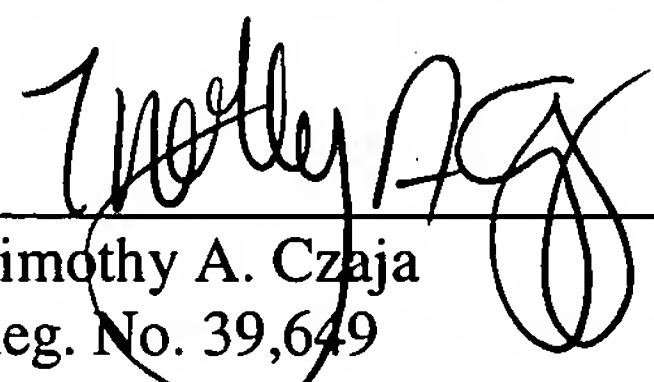
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Timothy A. Czaja
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By 

Name: Timothy A. Czaja